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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/692,084	08/08/1996	MOSES RODRIGUEZ	1199-1-001-C	3108

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EXAMINER	
DUFFY, PATRICIA ANN	
ART UNIT	**PAPER NUMBER**
1645	37

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
08/692,084	Rodriguez et al
Examiner	**Art Unit**
Patricia A. Duffy	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Dec 2, 2002* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above, claim(s) *5-8 and 15-18* is/are withdrawn from consideration.

5) ☒ Claim(s) *20 and 21* is/are allowed.

6) ☒ Claim(s) *1-4, 9-14, 19, and 22* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-22* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Response to Amendment

1. The amendment filed 12-2-02 has been entered into the record. Claims 1-4, 9-14, 20, 21 and 22 are under examination. Newly submitted claim 24 has been renumbered as claim 22 pursuant to 37 CRF 1.126. Claims 5-8 and 15-17 have been withdrawn from consideration. Claims 20 and 21 are allowed.

2. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

3. This application contains claims 5-8 and 15-17 drawn to an invention nonelected with traverse in Paper No. 7, mailed 6-19-97. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Rejections Maintained

Double Patenting

4. Claim 19 and new claim 22 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,591,629. Although the conflicting claims are not identical, they are not patentably distinct from each other the monoclonal antibody species set forth therein anticipates is the parent molecule of the antigen binding fragment of SCH 79.08 claimed and as such the antigen binding-fragment of the monoclonal antibody SCH 79.08 is an obvious variant. Moreover, the SCH 79.08 monoclonal autoantibody itself anticipates the claim in regard to the now generic "monoclonal autoantibody capable of inducing remyelination" or monoclonal synthetic autoantibody.

The rejection is maintained, no attempt was made to obviate this rejection.

5. Claims 1-4, 9-14, and 19 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of stimulating remyelination or treating a demyelinating disease in a mammal by administering to a mammal an effective amount of monoclonal autoantibodies that induce remyelination of central nervous system axons, the specific monoclonal autoantibodies: A2B5, SCH 79.08 and synthetic monoclonal autoantibodies, monoclonal autoantibodies 01, 04, HNK-1 are not enabled for reasons made of record in Paper No. 9, mailed 10-2-97, Paper No. 15, mailed 3-16-99 and in Paper No. 32, mailed 5-7-01.

Applicants arguments have been carefully considered but are not persuasive. Applicants again argue that monoclonal antibody clones 01, 04 and HNK-1 are publicly available. As to HNK-1, Applicants provide evidence Attached as Exhibit I, that as indicated in the prior Exhibit D, ATCC offers the HNK-1 clone for sale as deposited by Abo et al. Applicants indicate that Exhibit I is attached to the response, however, Exhibit I has apparently become detached from the response and a copy of the catalogue is not available to the examiner.

As to the 01 and 04 clones. Applicants is claiming the use of 01 and 04 hybridoma clones specifically, not any other clone that binds the same antigen. Applicants clearly miss this point. Exhibits do not provide for the public availability or on sale of the antibody produced by hybridoma clone 01 and clone 04 as described by the art of record (Kettenmann et al (Neuroscience Lett, 1985, 54(2-3):195-9). Other monoclonal antibody clones cited in the Roche and Chemicon documents do not fulfill the deposit requirement/pubic availability issue with respect to these specific hybridoma clones. Applicants specification references specific hybridoma clones not monoclonal antibodies

that bind the same antigen. Applicants evidence does not speak to the "O1 or O4" specifically named clones of Kettenmann et al, but "look-alikes" that bind the same antigen. It is noted that Applicants' are specifically claiming monoclonal antibody clones "O1" and "O4". They are not claiming any monoclonal that binds the "O1" or "O4" oligodendrocyte antigens as is provided by Applicants evidence. Applicants' have not provided deposit information for monoclonal antibody clones "O1" or "O4" as produced by hybridomas of that name, as are specifically claimed. The monoclonal antibody clones "O1" or "O4" are specific clones produced by others, see for example, Kettenmann et al., Neuroscience Letters, 54(2-3):195-199, March 15, 1985 and Bastmeyer et al., Neuroscience Lett, 101(2):127-32, June 19, 1989. The references in the art provide for specific monoclonal antibody clones entitled "O1" or "O4". Applicants are claiming the use of monoclonal antibodies produced by these specific clones, not by other clones that bind the same antigen as the monoclonal antibodies specifically known to the art at monoclonal antibody clones "O1" or "O4". Applicants argue that the "O1" or "O4" antibodies of Roche that are publicly available were those used by applicants. Applicants arguments were also not found persuasive, because the specification describes lists the "O1" and "O4" with other *specific monoclonal antibody hybridoma clones*. Consequently, the only reasonable interpretation of the passage as set forth in the specification is that applicants intended monoclonal antibody clone "O1" or "O4" as described in the art. Applicants' specification does not direct one of skill in the art to either the Roche or Chemicon antibodies, or monoclonal antibodies that bind the "01" or "04" antigens as alleged. The specification directs one to specific monoclonal antibodies "O1" and "O4" of the art and monoclonal antibodies that bind the O1 or O4 antigen as is clearly argued by Applicants and presented as evidence. Since the claims are to a specific exact clone, it is that specific clone, not a similar-binding

one, producing that exactly identical antibody which is required to be deposited. The record indicates that one skilled in the art would recognize that a fair reading of the passage in the specification indicates that applicants were discussing specific monoclonal antibody clones, not any monoclonal antibody that bound the same antigen. Applicants arguments remain not persuasive.

The as drawn to isolated to administration of monoclonal autoantibodies or monoclonal autoantibodies that are synthetic and that induce remyelination of central nervous system axons are enabled.

The rejection is maintained.

6. The rejection of claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Abo et al (J. Immunol., 127:1024-1029, 1981) or American Type Culture Collection Catalog, 1992, page 435 is maintained for reasons made of record.

Applicants argument has been carefully considered but is not persuasive. The claim is drawn to a product. Applicants argue that the function of the HNK-1 antibody of the prior art was not known and its was Applicants specification that teaches the use in remyleination and function as an autoantibody.. This is not persuasive, for product claims, it is well held by the courts that "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art... However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art". Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999). Because applicants are arguing newly

discovered functional characteristics of a known composition of the art, the reasoning is unpersuasive.

The rejection is maintained.

New Rejections Based on Amendment

7. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 22, the claim is indefinte because it recites selected from the group, but a group is not listed. A single selection is not a group and therfore the claim is internally inconsistent.

Status of Claims

8. Claims 1-4, 9-14, 19 and 22 stand rejected. Claims 20 and 21 are allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy, Ph.D. whose telephone number is (703) 305-7555. The examiner can normally be reached on Monday-Thursday and Saturday from 10:30 AM to 7:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached at (703) 308-3909.

Patricia A. Duffy, Ph.D.
February 21, 2003

Pat. a. Duffy
Patricia A. Duffy, Ph.D.
Primary Examiner
Group 1600